IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

THE MEDICINES COMPANY,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. 11-cv-1285
	)	
MYLAN INC., MYLAN PHARMACEUTICALS INC., and BIONICHE PHARMA USA, LLC,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

AMY J. ST. EVE, District Court Judge:

This is a patent infringement action by The Medicines Company ("TMC") against Defendants Mylan, Inc., Mylan Pharmaceuticals Inc. and Bionche Pharma USA, LLC alleging infringement of United States Patent No. 7,582,727 (the "'727 patent"), a product patent.[1] In advance of trial, Defendants move to preclude three TMC experts, Dr. Alexander Klibanov, Gerald Mossinghoff, and Anthony Flammia, from offering opinions that assume the asserted claims in the '727 patent require the invention to meet specified maximum Asp^9-bivalirudin impurity levels only "consistently." (*See* R. 342.) Defendants claim that the opinions at issue are inconsistent with TMC's argument on summary judgment that the asserted claims do not contain a "consistently" limitation, and judicial estoppel therefore precludes TMC from introducing these opinions at trial. (*See* R. 343.) For the following reasons, the Court grants Defendants' motion in part, denies it in part, and reserves ruling until trial in part.

[1] The Court previously granted Defendants' summary judgment motion as to United States Patent No. 7,598,343 (the "'343 patent"). (*See* R. 309.)

BACKGROUND

I. The '727 Patent

The '727 patent is a product patent that pertains to pharmaceutical formulations of a drug product comprising bivalirudin as the active ingredient. Bivalirudin is the active ingredient in Angiomax®, an injectable anticoagulant used in patients with unstable angina who are undergoing percutaneous transluminal coronary angioplasty. (R. 1, Compl. ¶¶ 11, 13.) TMC has sold Angiomax® since 2001.

Before expiration of the '727 patent, Mylan submitted Abbreviated New Drug Application ("ANDA") No. 202471 to the U.S. Food and Drug Administration ("FDA"), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of a generic equivalent to Angiomax®. TMC claims that the bivalirudin drug product proposed in Mylan's ANDA infringes claims 1-3, 7-10, and 17 of the '727 patent. Claim 1 is an independent claim, and the remaining asserted claims depend on Claim 1. Claim 1 states:

> Pharmaceutical batches of a drug product comprising bivalirudin (SEQ ID NO: 1) and a pharmaceutically acceptable carrier for use as an anticoagulant in a subject in need thereof, wherein the batches have a maximum impurity level of Asp^9-bivalirudin that does not exceed about 0.6% as measured by HPLC.

Each asserted claim contains a limitation requiring the pharmaceutical batches at issue to have "a maximum impurity level of Asp^9-bivalirudin that does not exceed about 0.6%" or less.[2]

II. Procedural History

In June 2013, Defendants moved for summary judgment of non-infringement or, in the alternative, invalidity. (*See* R. 276.) One of the issues Defendants raised on summary judgment was whether the asserted claims require the invention to meet the maximum Asp^9 impurity levels recited in the patent all of the time or only "consistently." Defendants argued that TMC's claim

[2] Claims 2 and 3 require that the maximum impurity level of Asp^9-bivalirudin not exceed about 0.4% or 0.3%, respectively.

fails under either interpretation. If the asserted claims require that *all* pharmaceutical batches meet the maximum Asp[9] impurity levels, Defendants argue that TMC's infringement claim fails because TMC cannot prove that Mylan's proposed bivalirudin product will always have maximum Asp[9] impurity levels below about 0.6%. (*See* R. 276, Defs. Summ. Jdgmt. Br. at 20-21.) If, on the other hand, the asserted claims require the pharmaceutical batches to meet the maximum Asp[9] impurity levels only "consistently,"[3] Defendants argue that the asserted claims are invalid as anticipated by TMC's Original Angiomax® product, which had a maximum Asp[9] impurity level below about 0.6% more than 87% of the time. (*See id.* at 21-24.)

In response to Defendants' anticipation argument, TMC argued against reading a "consistently" limitation into the asserted claims. (*See* R. 290, TMC Summ. Jdgmt. Resp. Br. at 30-31.) TMC pointed out (as Defendants also had) that the term "consistently" appears nowhere in the asserted claims and reading the term into the claims would improperly rewrite them. (*Id.* at 31.) Based on TMC's representations, the Court decided not to address Defendants' anticipation argument on the merits because, in the end, neither side had advocated for reading "consistently" into the asserted claims. (*See* Summ. Jdgmt. Op. at 42 n.9.) Both sides, in fact, expressly argued *against* interpreting the claims as containing a "consistently" limitation. (*See id.*)

In the present motion, Defendants argue that the Court should prevent TMC and its experts from backsliding on TMC's argument on summary judgment that the asserted claims do

[3] The '727 patent defines "consistently" as

> indicat[ing] that about 85% of the pharmaceutical batch(es) or pharmaceutical formulation(s) have a specific characteristic, or . . . about 90% of the pharmaceutical batch(es) or pharmaceutical formulation(s) have the characteristic, or about 99% of the pharmaceutical batch(es) or pharmaceutical formulation(s) have said characteristic, or 100% of the pharmaceutical batch(es) or pharmaceutical formulation(s) have said characteristic.

('727 patent at col. 13, ll. 13-24.)

not contain a "consistently" limitation. Specifically, Defendants seek to exclude TMC's experts from offering testimony "premised upon the assumption that the '727 patent claims require that the Asp[9] maximums recited therein be met only 'consistently.'" (R. 342, Defs Mot. at 1.)

LEGAL STANDARD

"The admissibility of expert testimony is governed by Federal Rule of Evidence 702 and the Supreme Court's opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993)." *Lewis v. Citgo Petroleum Corp.*, 561 F.3d 698, 705 (7th Cir. 2009). Rule 702 provides, in relevant part, that "[i]f scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion . . . ." *Id.* *See also Happel v. Walmart Stores, Inc.*, 602 F.3d 820, 824 (7th Cir. 2010).

Under the expert-testimony framework, courts perform the gatekeeping function of determining whether the expert testimony is both relevant and reliable prior to its admission at trial. *See id.*; *Power Integrations, Inc. v. Fairchild Semiconductor Int'l., Inc.*, 711 F.3d 1348, 1373 (Fed. Cir. 2013). In doing so, courts "make the following inquiries before admitting expert testimony: first, the expert must be qualified as an expert by knowledge, skill, experience, training, or education; second, the proposed expert must assist the trier of fact in determining a relevant fact at issue in the case; third, the expert's testimony must be based on sufficient facts or data and reliable principles and methods; and fourth, the expert must have reliably applied the principles and methods to the facts of the case." *Lees v. Carthage College*, 714 F.3d 516, 521-22 (7th Cir. 2013); *see also Stollings v. Ryobi Tech., Inc.*, 725 F.3d 753, 765 (7th Cir. 2013); *Power Integrations*, 711 F.3d at 1373.

ANALYSIS

I. Judicial Estoppel

Defendants seek to exclude Dr. Alexander Klibanov, Gerald Mossinghoff, and Anthony Flammia[4] from offering opinions at trial that assume the asserted claims require the invention to meet the maximum Asp[9] impurity levels recited in the patent only "consistently." Defendants assert that because TMC argued against reading the asserted claims as containing a "consistently" limitation to avoid summary judgment, TMC cannot now do an about-face and rely on that interpretation at trial to prove infringement. (*See* R. 343, Defs. Mem. at 7.) As a general matter, the Court agrees that judicial estoppel prevents TMC from offering opinions at trial based on an interpretation of the asserted claims that TMC repudiated on summary judgment.

Judicial estoppel "prevents parties from playing 'fast and loose' with the courts by prevailing twice on opposing theories." *United States v. Hallahan,* 744 F.3d 497, 510 (7th Cir. 2014) (quoting *In re Airadigm Commc'ns, Inc.,* 616 F.3d 642, 661 (7th Cir. 2010)); *New Hampshire v. Maine,* 532 U.S. 742, 749, 121 S. Ct. 1808, 149 L. Ed. 2d 968 (2001). Although the doctrine usually applies to successive suits, it also precludes "a party from prevailing in one phase of a case on an argument and then relying on a contradictory argument to prevail in another phase." *In re Airadigm Commc'ns, Inc.,* 616 F.3d at 661; *see also New Hampshire v. Maine,* 532 U.S. at 749, 121 S. Ct. 1808, 149 L. Ed. 2d 968 (quoting *Pegram v. Herdrich,* 530 U.S. 211, 227 n.8, 120 S. Ct. 2143, 147 L. Ed. 2d 164 (2000)); *Walton v. Bayer Corp.,* 643 F.3d 994, 1002-03 (7th Cir. 2011). Courts typically examine three factors in determining whether

[4] On March 28, 2014, the Court granted Defendants' motion to exclude in full Anthony Flammia's opinions regarding commercial success. (*See* R. 406.) The Court, therefore, denies as moot Defendants' motion to preclude Mr. Flammia from offering opinions based on the assumption that maximum Asp[9] impurity levels recited in the patent must be met only "consistently."

judicial estoppel applies:

> (1) whether the party's later position was "clearly inconsistent" with its earlier position; (2) whether the party against whom estoppel is asserted in a later proceeding has succeeded in persuading the court in the earlier proceeding; and (3) whether the party "seeking to assert an inconsistent position would derive an unfair advantage or impose an unfair detriment on the opposing party if not estopped."

Hallahan, 744 F.3d at 510-511 (quoting *In re Airadigm Commc'ns, Inc.*, 616 F.3d at 661); *see also New Hampshire v. Maine,* 532 U.S. at 750-51, 121 S. Ct. 1808, 149 L. Ed. 2d 968. Because the purpose of judicial estoppel is to protect the integrity of the judicial process, courts have discretion in deciding whether to invoke the doctrine. *See New Hampshire v. Maine*, 532 U.S. at 751, 121 S. Ct. 1808, 149 L. Ed. 2d 968.

The pertinent factors weigh in favor of applying judicial estoppel in this case to prevent TMC's experts from offering opinions at trial premised on an interpretation of the asserted claims as requiring the maximum Asp^9 impurity levels recited in the patent to be met only "consistently." First, this interpretation of the asserted claims is "clearly inconsistent" with TMC's argument earlier in the litigation that the asserted claims do not contain a "consistently" limitation. "[I]t is axiomatic that claims are construed the same way for both invalidity and infringement." *Source Search Techs., LLC v. LendingTree, LLC*, 588 F.3d 1063, 1075 (Fed. Cir. 2009). TMC, therefore, cannot argue against interpreting the claims as containing a "consistently" limitation in order to avoid summary judgment of invalidity and then reverse course later in the proceeding and argue in favor of that repudiated interpretation for purposes of infringement. Second, the Court relied on TMC's argument that the asserted claims do not contain a "consistently" limitation in declining to address Defendants' anticipation argument on the merits on summary judgment. Third, TMC's earlier position allowed it to avoid a potential determination that the asserted claims are invalid as anticipated by prior art. Allowing TMC to

rely on one interpretation of the asserted claims to avoid Defendants' invalidity argument but another, contradictory interpretation to prove infringement would condone exactly the type of gamesmanship that judicial estoppel seeks to prevent. *See New Hampshire v. Maine*, 532 U.S. at 749-51, 121 S. Ct. 1808, 149 L. Ed. 2d 968; *Continental Ill. Corp. v. C.I.R.*, 998 F.2d 513, 518 (7th Cir. 1993) ("A party can argue inconsistent positions in the alternative, but once it has sold one to the court it cannot turn around and repudiate it in order to have a second victory . . . ."); *Transclean Corp. v. Jiffy Lube Int'l, Inc.*, 474 F.3d 1298, 1307 (Fed. Cir. 2007) ("[A] party may be judicially estopped from asserting clearly inconsistent positions on claim construction . . . .").

II. Expert Opinions at Issue

Before deciding whether judicial estoppel excludes the expert opinions at issue in Defendants' motion, the Court must determine whether those opinions are, in fact, inconsistent with TMC's interpretation of the claims on summary judgment. The Court turns to Dr. Klibanov's opinions first.

A. Dr. Klibanov

Dr. Klibanov is a Professor of Chemistry and Bioengineering at the Massachusetts Institute of Technology, where he has taught and conducted research for over 33 years. He has a Master's of Science degree in Chemistry and a Ph.D. in Chemical Enzymology from Moscow University. He has published over 300 scientific papers in various areas of chemistry; he serves on editorial boards for twelve scientific journals; and he has earned numerous professional awards and honors. In addition to teaching and conducting research at M.I.T., Dr. Klibanov has served as a consultant to pharmaceutical, medical device, chemical, and biotechnology companies. He also has founded and served on scientific advisory boards and boards of directors of several biopharmaceutical companies.

Defendants seek to exclude the opinions contained in paragraphs 42-44, 87, 118, 121, 123, 125-26, 141-42, 195, and 205 of Dr. Klibanov's March 8, 2013 rebuttal report (R. 362-2, Greb Decl. Ex. 6, Klibanov Rebuttal Rep.). (*See* Defs. Mem. at 8.) In paragraphs 42-44 of his rebuttal report, Dr. Klibanov explains the basis of his disagreement with Defendants' interpretation of the maximum Asp^9 impurity limitation contained in the asserted claims. Defendants' expert, Dr. David Auslander, stated in his report that, in light of the Court's claim construction order and the patent specification, he understood the asserted claims to "require that a compounding process must never produce a batch that exceeds the claimed maximum impurity levels or reconstitution times" recited in the patent. (*See* Klibanov Rebuttal Rep. ¶ 41 (quoting Auslander Rep. ¶ 26).) Dr. Klibanov disagrees with Dr. Auslander's interpretation for two reasons: (1) "the '727 patent does not require that a compounding process 'must never' produce a batch exceeding the claimed maximum impurity levels or reconstitution times[;]" and (2) a person skilled in the art "would understand that human error can and does sometimes occur even if the process is followed during manufacturing," (*Id.* ¶ 42.)

With respect to the second reason, Defendants agree that "where a high Asp^9 reading is the proven result of human or laboratory error, such fact would not cause the claims to be avoided." (*See* R. 10, Defs. Reply Br. at 10 n.4.) Defendants represent that they do not seek to exclude Dr. Klibanov from offering opinions based on this issue at trial. Rather, Defendants seek to exclude his opinion regarding what the '727 patent requires. That opinion, on its face, does not necessarily contradict TMC's earlier argument against reading "consistently" into the asserted claims. Dr. Klibanov may have based his opinion on an assumption that the asserted claims contain a "consistently" limitation, in which case, judicial estoppel would apply, but he also may have based his opinion on the need to account for human error, which Defendants

concede remains fair game. TMC argues that the latter interpretation of Dr. Klibanov's opinion is correct. (*See* R. 444, TMC Resp. Br. at 7.) Because it is not entirely clear whether Dr. Kliobanov's opinion rests on the repudiated interpretation of the asserted claims—and because the need for the Court to determine the admissibility of Dr. Klibanov's opinions in advance of trial is lessened where, as here, the Court will serve as the trier of fact, *see In re Salem*, 465 F.3d 767, 777 (7th Cir. 2006); *Metavente Corp. v. Emigrant Sav. Bank*, 619 F.3d 748, 760 (7th Cir. 2010)—the Court reserves ruling on Defendants' motion with respect to paragraph 42 until trial. The Court also reserves ruling on Defendants' motion with respect to paragraphs 44 and 123, which merely incorporate or repeat the statements in paragraph 42. The Court will rule on these aspects of Defendants' motion after hearing from Dr. Klibanov about the assumption upon which these opinions rest.

Next, Defendants seek to exclude paragraphs 87, 118, and 121 of Dr. Klibanov's rebuttal report. These paragraphs state:

- I understand that [TMC's] inventors developed new and improved pharmaceutical batches of a drug product with more consistent and minimized levels of the Asp^9 impurity and a new and improved process for making the same. (Klibanov Rebuttal Rep. ¶ 87.)

- Moreover, Ben Venue did ***not*** solve the problem of inconsistent and too high Asp^9 impurity levels in Original Angiomax®. As discussed above, although Ben Venue knew in 2005 that lot 716184 had excessive levels of the Asp^9 impurity, its suggestions to fix this problem did not work; shortly thereafter, lot 896002 also had excessive levels of the impurity. (*Id.* ¶ 118 (emphasis in original).)

- Also, although Dr. Auslander asserts that Ben Venue conceived the inventions (¶¶ 109 and 134 of his report), he admits that Ben Venue's ideas did not work because a subsequent lot, 896002, had a very high level (2.3%) of the Asp^9 impurity in bivalirudin. *See* Auslander Report ¶¶ 61-65. I do not see how Dr. Auslander's admissions regarding Ben Venue's failure to solve the problem of inconsistent and too high Asp^9 levels can be reconciled with his opinions regarding Ben Venue's alleged role in the "conception" of the inventions. Auslander Report ¶¶ 109, 134. (*Id.* ¶ 121.)

TMC argues that the Court should not exclude these opinions because they concern the problem that the invention solved, not the proper interpretation of the asserted claims. (*See* TMC

Resp. Br. at 6-7.) The Court agrees. None of these opinions discuss the scope or meaning of the asserted claims. Rather, they identify one of the problems inherent in the old compounding process—*e.g.*, that it resulted in pharmaceutical batches with inconsistent impurity levels. Identifying that the problem the invention attempts to solve concerned the inconsistent levels of impurities in prior art does not equate to importing a "consistently" limitation into the asserted claims. The opinions in paragraphs 87, 118, and 121, therefore, are not "clearly inconsistent" with TMC's position on summary judgment. *See In re Airadigm Commc'ns, Inc.*, 616 F.3d at 661. Accordingly, the Court denies Defendants' motion with respect to paragraphs 87, 118, and 121 of Dr. Klibanov's rebuttal report.

Next, Defendants seek to exclude Dr. Klibanov's opinions in paragraphs 125 and 126 of his rebuttal report. In theoe paragraphs, Dr. Klibanov responds to Dr. Auslander's opinion that the '727 patent fails to satisfy the enablement requirement because it does not teach a person of ordinary skill how to manufacture pharmaceutical batches that will "never exceed a maximum of 0.6% Asp^9." (*See* Klibanov Rebuttal Rep. ¶¶ 122-127 (quoting Auslander Rep. ¶ 136).) Dr. Auslander based his enablement opinion on failed Lot 1344985, which, although purportedly manufactured using the new compounding process, had an Asp^9 impurity level of 1.5%. (*See id.*) Dr. Auslander argued that this failed lot showed that even the new compounding process did not teach how to manufacture batches that will never exceed the maximum Asp^9 impurity levels recited in the patent. (*See id.*) Dr. Klibanov disagreed, stating, in relevant part:

- Furthermore, Dr. Auslander's aforementioned characterization of the invention is contradicted as the patents-in-suit state (emphasis added):

> In various embodiments of the present invention, the pharmaceutical batch(es) or pharmaceutical formulation(s) generated by the compounding process may be characterized by ***consistently having*** a maximum impurity level of Asp^9-bivalirudin not exceeding about 1.5%, or not exceeding about 1%, or not exceeding about 0.6%, or not exceeding about 0.4%, or not

exceeding about 0.3%.

'727 patent, col. 13: ll. 25-31; *see also id.* at col. 13: ll. 10-24.

Thus, not ***all*** pharmaceutical batches must have levels of the Asp^9 impurity at or below about 0.6%. (Klibanov Rebuttal Rep. ¶ 125 (emphasis in original).)

- For Improved Angionmax®, all lots that followed the Improved Process had Asp^9 levels not exceeding about 0.6%. Even if the Asp^9 impurity value of 1.5% for lot 1344985 is considered (and as discussed in section XVIII(A) below it is my opinion that it was not manufactured using the Improved Process), the Improved Process still consistently minimizes the Asp^9 impurity compared to Original Angiomax®. *See* Tables 6 and 7 of the '727 patent; *see also* native file MYL4583534; native file MEDMYL 4562777. (*Id.* ¶ 126.)

TMC argues that the Court should not exclude these opinions because they relate to the second step in the infringement analysis, *i.e.*, comparing the accused device to the construed claims, rather than claim construction. (*See* TMC Resp. Br. at 8-11); *see also Proveris Scientific Corp. v. Innovasystems, Inc.*, 739 F.3d 1367, 1372 (Fed. Cir. 2014) ("In conducting an infringement analysis, a court must first determine the meaning of any disputed claim terms and then compare the accused device to claims as construed.").

TMC's argument is unavailing. Dr. Klibanov's opinion in paragraph 125 that "not ***all*** pharmaceutical batches must have levels of the Asp^9 impurity at or below about 0.6%" pertains to the meaning and scope of the asserted claims, which is a classic claim construction determination. *See id.*; *see also Lighting Ballast Control LLC v. Philips Elecs. N. Am. Corp.*, 744 F.3d 1272, 1284-85 (Fed. Cir. 2014) (claim construction "establishes the metes and bounds of the claims that define the patent right" and provides "a legal statement of the scope of the patent right"). The fact that Dr. Klibanov quotes the patent specification as the basis for his opinion further evidences that his opinion concerns claim construction issues. *See, e.g., Lighting Ballast Control LLC v. Philips*, 744 F.3d at 1284-85; *see also Phillips v. AWH Corp.*, 415 F.3d 1303, 1313-15 (Fed. Cir. 2005) ("[T]he specification 'is always highly relevant to the claim

construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" (citation omitted)).

Furthermore, the emphasis Dr. Klibanov put on the words "***consistently having***" in his quotation of the '727 patent specification shows that his interpretation of the claims rests on reading "consistently" into them. This approach is "clearly inconsistent" with TMC's position on summary judgment that the asserted claims do not contain a "consistently" limitation. Judicial estoppel, therefore, prevents TMC from introducing this opinion at trial. *See New Hampshire v. Maine,* 532 U.S. at 749-51, 121 S. Ct. 1808, 149 L. Ed. 2d 968; *In re Airadigm Commc'ns, Inc.*, 616 F.3d at 661.

Dr. Klibanov's opinion in paragraph 126 also assumes that the asserted claims contain a "consistently" limitation. The takeaway from this opinion is that even if failed Lot 1344985 was manufactured using the new compounding process (a fact which Dr. Klibanov disputes), the Asp^9 impurity levels from that lot alone would not render the '727 patent invalid because the patent required the maximum Asp^9 impurity levels to be met only "consistently." (*See* Klibanov Rebuttal Rep. ¶ 126.) Because this interpretation of the maximum Asp^9 impurity requirements contradicts TMC's earlier argument on summary judgment, judicial estoppel prevents TMC from introducing Dr. Klibanov's opinion in paragraph 126 at trial.[5] *See New Hampshire v. Maine,* 532 U.S. at 749-51, 121 S. Ct. 1808, 149 L. Ed. 2d 968; *In re Airadigm Commc'ns, Inc.*, 616 F.3d at 661.

Next, Defendants seek to exclude Dr. Klibanov's opinions in paragraph 195 of his rebuttal report. In paragraph 195 and the surrounding paragraphs, Dr. Klibanov responds to the opinions of Defendants' expert, Nancy Linck, regarding whether the 1.5% Asp^9 impurity level of

[5] The Court also excludes Dr. Klibanov's opinion in paragraph 142, which incorporates and relies on the opinions in paragraphs 125-26 that the Court has excluded.

failed Lot 1344985 was material and should have been disclosed to the U.S. Patent and Trademark Office ("USPTO"). (*See* Klibanov Rebuttal Rep. ¶ 191-95.) Dr. Klibanov opines that the failed lot was not material because the drug manufacture, Ben Venue, did not follow the new compounding process in formulating that batch. (*Id.* at 191-94.) Moreover, Dr. Klibanov opines in paragraph 195, "even if the Asp^9 value of 1.5% for lot 1344985 is considered, it is still not material because Improved Angiomax® nonetheless has ***consistently*** minimized Asp^9 levels compared to Original Angiomax®." (*Id.* at 195.) The takeaway from this paragraph, similar to the takeaway from paragraph 126, is that even if Lot 1344985 was manufactured using the new compounding process, the Asp^9 impurity levels from that failed lot alone would not be material to the patent examiner because the asserted claims required the maximum Asp^9 impurity levels to be met only "consistently." (*Id.*) This contradicts TMC's position on summary judgment, and thus, judicial estoppel prevents TMC from offering Dr. Klibanov's opinion in paragraph 195 at trial.

Judicial estoppel also prevents TMC from introducing at trial Dr. Klibanov's opinion that "Improved Angiomax® has consistently lower Asp^9 levels compared to Original Angionmax®" (*See* Klibanov Rebuttal Rep. ¶ 205.) In paragraph 205, Dr. Klibanov simply paraphrases his opinion in paragraph 195. Because the Court has excluded Dr. Klibanov's opinions in paragraph 195, it also excludes his opinions in paragraph 205.

B. Mr. Mossinghoff

Mr. Mossinghoff is a practicing attorney who specializes in intellectual property law. He served as a patent examiner in the USPTO for five years, as the USPTO's Director of Legislative Planning for two years, and as Commissioner of Patents and Trademarks for four years. He also has served three terms on the Patent Public Advisory Committee and was elected as Chairman of

the General Assembly of the United Nations World Intellectual Property Organization. In addition to his private law practice, Mr. Mossinghoff teaches intellectual property law at the George Washington University Law School. TMC purportedly intends to use Mr. Mossinghoff as an expert "on the rules and procedural requirements governing the filing and prosecution of patent applicants in the USPTO and the grant of U.S. patents by the USPTO, and on the duty of candor and good faith that those substantively involved in the preparation and prosecution of a patent application owe to the USPTO." (*See* R. 364-1, Greb Decl. Ex. 9, Mossinghoff Rep. ¶ 4.)

Defendants seek to exclude Mr. Mossinghoff's opinions in paragraphs 21-24 and 37-38 of his report, which rely on Dr. paragraphs 125, 191-94, and 195 of Dr. Klibanov's rebuttal report. (*See* Defs. Mem. at 8.) Because judicial estoppel prevents TMC from introducing at trial Dr. Klibanov's opinions in paragraphs 125 and 195 of his rebuttal report, it also prevents Mr. Mossinghoff from offering opinions based on those excluded opinions.

The Court has not precluded Dr. Klibanov from offering the opinions in paragraphs 191-94 of his rebuttal report concerning whether Ben Venue correctly followed the new compounding process in manufacturing failed Lot 1344985. To the extent Mr. Mossinghoff's challenged opinions rely on Dr. Klibanov's opinions in paragraphs 191-94, therefore, he may still offer those opinions at trial.

CONCLUSION

For the reasons explained above, the Court grants in part, denies in part, and denies in part as moot Defendants' motion to preclude TMC's experts from offering opinions that assume the asserted claims in the '727 patent require the invention to meet maximum Asp^9-bivalirudin impurity levels only "consistently."

Dated: May 15, 2014

ENTERED

AMY J. ST. EVE
U.S. District Court Judge